Exhibit N

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
X

PHARMACEUTICAL SOCIETY OF THE STATE OF NEW YORK, INC.,

Plaintiffs

-against-

AFFIDAVIT

MARIO M. CUOMO, Governor of the State of New York, and CESAR A. PERALES, Commissioner, New York State Department of Social Services,

Defendants.
X

STATE OF NEW YORK)
) ss.:
COUNTY OF NEW YORK)

I, MARY ALICE BRANKMAN, being duly sworn do depose and say:

1. I am the Director of the Bureau of Ambulatory Services, Inpatient Care and Contracts in the Division of Medical Assistance of the New York State Department of Social Services (hereinafter the Department). As such, I am familiar with the Federal and State policies with respect to reimbursement by the Medicaid program for prescription drugs. I make this affidavit in support of the Defendants' motion for entry of an order in conformity with the decisions issued by the United States District Court, Southern District of New York, and the Court of Appeals for the Second Circuit.

2. On February 24, 1988, Plaintiff, the Pharmaceutical Society of the State of New York (PSSNY), sought a temporary restraining order in the United States District Court for the Southern District of New York

seeking to restrain the Defendants from enforcing an amended regulation. The basis for the Plaintiff's motion was a Stipulation of Settlement and Order that had been entered into by the parties in 1978. (See Exhibit A to Plaintiff's Notice of Motion.)

3. On February 29, 1988, Judge Kevin T. Duffy, United States District Judge, issued an Order restraining the Defendants from violating the terms of the 1978 Stipulation of Settlement entered between the parties and from enforcing 18 NYCRR 505.3(h)(2)(v), such Order to be "in effect until further Order of this Court." (See Exhibit B to Plaintiff's Notice of Motion.)

4. The Defendants were granted a stay of this Order pending appeal and the Department implemented the amended regulation on March 1, 1988.

5. The Department also continued with its plans to reconstitute the Pharmacy Advisory Committee (PAC). When a sufficient number of nominations were received and the required investigations completed, the Department reconstituted the PAC with nine members, pursuant to the terms of the 1978 Stipulation of Settlement, and the committee held its first meeting on March 23, 1988. Five members of the PAC are also members of the Plaintiff organization, PSSNY.

6. During the first meeting of the PAC, there was a comprehensive discussion of the Department's reimbursement methodology for federally upper limited drugs and the rationale for implementing such a methodology. There was an extensive question and answer session, as recorded in the minutes, and the Department reiterated its desire to obtain information from the industry which it has so far been unsuccessful in obtaining. (See Exhibit G to Plaintiff's Notice of Motion.) Since then, the Department met with the PAC on a regular basis

(April 28, 1988; July 20, 1988; October 6, 1988; January 11, 1989; and April 12, 1989). The last meeting was held on June 21, 1989. Also, the annual public hearing on the subject of Medicaid pharmaceutical dispensing fees and the estimated acquisition cost (EAC) of prescription drugs as required under the Stipulation was held on September 26, 1988.

The Department did not receive any suggestions from the PAC for modifying 18 NYCRR 505.3(h)(2)(v) or implementing a different reimbursement methodology. Therefore, the Department continued to implement the same reimbursement methodology.

7. On September 2, 1988, the United States Court of Appeals for the Second Circuit issued a decision, with one Judge dissenting in a separate opinion, affirming Judge Duffy's Order. (See Exhibit C to Plaintiff's Notice of Motion.) Defendants decided not to appeal the decision.

8. Pursuant to the affirmed decision, the Department initiated plans to reimburse the pharmacies. As stated in the Memorandum of Law in Support of Defendants-Appellants' Motion for a Stay Pending Appeal, (see Exhibit 1), the Department has the capability through its payment system to retroactively adjust payments made to pharmacies, although with some administrative difficulty, if pharmacies resubmitted bills for those prescription drugs which were impacted by the federal upper limits.

Upon receipt of the Court of Appeals' decision, the Department immediately began exploring possible approaches to implement the Court's decision and to reimburse the pharmacies. Several issues were addressed. First, the time period during which the pharmacies were incorrectly paid needed to be determined. Second, the method of adjusting prices given the Department's computer capabilities and limitations was given consideration. This involved extensive analysis of

the Department's computer system capabilities in the claims processing area and testing of various methods that may be utilized to automatedly and retroactively reimburse pharmacies which would be least burdensome to the pharmacies and fair to all pharmacies entitled to reimbursement. Primary consideration was given to the Department's pharmacy consultant staff who advised that, for many pharmacies, identifying the affected claims could be extremely difficult and time consuming. Third, the question of whether or not prices had to be updated for the affected period and if so the frequency of the updates was addressed. The Department is obligated to update prices at least quarterly. Fourth, the Department had to identify which drug prices were affected by the implementation of the federal upper limits.

9. Defendants stated in their Motion for a Stay Pending Appeal that "[t]he State is at risk of losing $820,000.00 per week if it must continue reimbursements under the former methodology." (See Page 5 of Exhibit 1.) Under the new Federal requirements, State payments for listed multiple source drugs could not exceed the total amount which a quantity of drugs would have cost under a specified upper limit set by the Health Care Financing Administration (HCFA), plus a reasonable dispensing fee.

The projected expenditure of $820,000.00 was based on a methodology for implementing the federal upper limits for all drugs reimbursed by the Department under the Medical Assistance program including brand name drugs. However, pursuant to a temporary restraining order issued on February 26, 1988 by the State Supreme Court, Albany County, in Abdelnour et al. v. Perales, Index No. 1139/88, the Department continued to pay EAC, which in New York is the average wholesale price (AWP), for brand

name drugs until the Department was able to implement the optional federal physician override provision. These prescriptions did not meet the federal requirements for a physician override provision. The state's regulation implementing the optional federal physician override provision was adopted by the Department to be effective February 1, 1989. Under the state's regulation, 18 NYCRR 505.3(h)(2)(v)(a), where the prescriber certifies that a brand name drug is medically necessary, payments will not be included in the calculation for compliance with the federal upper limits for multiple source drugs. Subsequent calculations based on extrapolation from actual payments revealed that retroactive reimbursement to all pharmacy providers as a result of the stay granted by the Court of Appeals for the Second Circuit will be approximately $602,000.00 per month.

10. Although the Department explored the feasibility of maintaining the existing reimbursement system and still meeting the federal upper limits, it was determined that if the State continued to reimburse drugs according to the current methodology, the State would not be able to conform to the new Federal requirements. See Affidavit of Gerard F. Nelligan in the Defendant's Motion for a Stay Pending Appeal.

The Department analyzed the proposed expenditure by identifying those drugs which were affected by the federal upper payment limits and comparing the reimbursement costs for those drugs for the period January to June, 1987 and what reimbursement would have been under the proposed upper limits for the same period.

The Department compared the actual expenditure and the projected expenditure for those drugs for which the federal upper limit is lower than New York's August 1987 EAC. The expenditure for these drugs for the

first 6 months of 1987 was $40,393,588.00; when the federal upper limits were substituted for the EAC, the comparable cost for that period of time was $18,957,321.00. (See Exhibit 2.) Therefore, for those drugs for which the federal upper limit is lower than New York's August 1987 EAC, the Department lowered the EAC to the federal upper limit. These drugs comprised 26% of the prescription drugs reimbursed by the Department. For those drugs for which New York's August 1987 EAC was lower than the federal upper limit, the actual expenditure for the first 6 months of 1987 was $3,741,713.00; when expenditure was projected for the same period of time at the federal upper limit prices, the figure was $13,675,841.00. (See Exhibit 3.) The Department maintained the EAC for these drugs. These drugs comprised 2% of the reimbursable drugs.

Applying the federal upper limits to the first group of drugs while maintaining the EAC for the second group of drugs was viewed as the most flexible methodology available. For all other drugs, comprising 72% of the drugs reimbursed by the medical assistance program, the former methodology was maintained, i.e. for brand name drugs and other multiple source drugs not affected by the federal upper limits, reimbursement was based on the lower of EAC plus a dispensing fee or the usual and customary price charged by the provider.

This methodology gave the Department the flexibility to readjust prices for those drugs which were brought to the attention of the Department as being unavailable for purchase in New York State at the upper limit price. Prior to implementation of the new regulation, PSSNY was informed of this flexibility and invited to submit a list of those drugs which they felt should be exempt from the federal upper limits.

11. The regulation, 18 NYCRR 505.3(h)(2)(v), implementing the federal upper limits, is necessary to comply with the Federal

requirements. The Department's methodology guarantees that the Department will not exceed the federal upper limits and at the same time gives the Department the flexibility to adjust prices where necessary.

12. On November 10, 1988 the Department received a letter dated October 31, 1988 from Michael Esemplare, President of PSSNY, urging that a meeting be arranged to resolve the litigation. (See Exhibit E of Plaintiff's Notice of Motion.) In good faith, the Department agreed to meet with members of the plaintiff organization. The Department also informed Mr. Esemplare by letter that it had formulated a plan to reimburse the pharmacies and that the plan would be submitted to the court and to the plaintiff when it is finalized. (See Exhibit 4.) The submission of the plan was pended in anticipation of and during discussions with the plaintiff in contemplation of a possible resolution to the litigation. To accommodate all parties, the first meeting was arranged for January 10, 1989. Subsequent meetings were held on January 24 and March 14.

During the months January through April, while the Department was engaged in discussions with the plaintiff, the plaintiff made extensive requests for information and data. The Department provided all the information and data which were within the capacity of the Department to provide.

13. In the meantime, the Department proceeded with designing, developing and testing a system to automatedly reimburse pharmacy providers the difference between EAC drug prices and the upper limit drug prices for the claims for the affected drugs. The automated method was determined to be the least burdensome adjustment process for the pharmacies; otherwise, pharmacies would have to go through all their

claims to identify and transmit to the Department those claims which need to be adjusted. On February 2, 1989, the Department requested MMIS to commence a special adjustment process to accomplish this.

The special adjustment process involves the extraction of all affected drug claims for the reimbursement period to create a new payment file. The Department would then insert the reimbursement price in effect on February 29, 1988, before the implementation of the federal upper limits, to the new file and generate a check for the difference between the amount the pharmacy would have been paid if the federal upper limits had not been implemented and the amount the pharmacy was already paid.

MMIS requested that the Computer Sciences Corporation (CSC), the Department's fiscal agent, develop a priority project to develop the general design specifications for the adjustment process. When the Department approved the general design specifications, CSC commenced to extract from their claim files all the affected claims. There were about one-half million claims from 3,244 pharmacies that resulted from this extraction and for which payment would need to be adjusted.

Also, during April and May of 1989, the Department proceeded to take steps to create a new drug price file reflecting updated EAC prices for the March-April 1989 time period. Prices for 1,675 drugs had to be manually updated; to accomplish this, a project request was made for technical support to create a replacement file. During June of 1989 this file was tested and approved for transmission to the fiscal agent for the purpose of adjusting the affected claims.

The final test of the adjustment process, conducted on June 17, 1989, revealed that because of the processing logic in the system, which is to pay the lower of the amount claimed by the pharmacy provider or the

amount in the reimbursement file, zero adjustments were generated. The system is currently being modified to override this problem and the checks will be forwarded to the pharmacies in the first available payment cycle.

14. At the end of May of 1989, the plaintiff served a notice of motion to enforce orders of the court.

The service of this motion was a surprise to the defendants because the Department was under the impression that the settlement negotiations were still on-going, and that the Department was expected to respond to the plaintiff's offer with an agreement or by making a counter-offer. There had been no resolution or settlement and the plaintiff had not indicated to the defendants that the plaintiff considered the defendant's time to respond to the plaintiff's offer was at an end. The defendants had been awaiting legislative action on a bill which had an impact on the defendants' response to the plaintiff's offer.

WHEREFORE, Defendants respectfully request the entry of an Order in this matter terminating the Defendants' obligations upon reimbursement to the pharmacies on an automated basis the amount lawfully owed to them; to wit, the difference between the EAC in effect on February 29, 1988 and the reimbursement rate in effect after implementation of the revised 18 NYCRR 505.3(h)(2)(v), for the period March 1, 1988 to April 22, 1988 when consultation with the reconstituted PAC was completed.

Mary Alice Brankman

MARY ALICE BRANKMAN

Sworn to before me this
22nd day of June, 1989

Notary Public
Qualified Albany County
Commission Expires 6-30-89